

**HL7 SPL Working Group Process Communication Forum Telecon
Wednesday, January 25, 2012**

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

UNII or SRS questions? Send to fda-srs@fda.hhs.gov

As of January 25, 2012: DailyMed has close to 34,000 SPL loaded.

Minutes:

- Follow up discussions from last meeting regarding product-establishment relationship

Pat's 'additional questions text' is appended to these minutes

<http://spl-work-group.wikispaces.com/file/view/20120104%20Min%20Update%20from%20DRLS%20Q%26A.pdf>

- Re-cap of off line discussions with DRLS for outstanding questions from ER/DL team
- Open questions
- PILLBOX update

Minutes:

Agenda:

- **New validation rule related to including product NDC code for each manufacturing establishment.**
 - **Implementation timing: Feb 1, 2012**
- Post-meeting note: The implementation of this validation rule has been postponed.
- We will be collecting your questions -- so that we can clarify the process prior to the implementation date.
- Other questions from the meeting and walk-ins

[There are a lot of details that will also be included in the ER/DL Subteam meeting minutes, expected to be released in the next week or so]

A validation rule will be implemented that will require establishments to reference the product NDCs. Each product NDC must be linked to at least one establishment. This will allow a way

to match -up the specific establishment to a specific product/NDC.

Each product in the SPL must be linked to at least one establishment in the establishment section.

- This rule has been in the validation rules since 2010; it will be enforced starting February 1, 2012.
- Implementation is particular to CDER-regulated products. CBER and Vet products are not currently required to provide this linkage.
- *Sponsors should check with their SPL software vendors to make sure that they have this functionality in the tool*
- Enter NDCs to the product level – not to the pack size level. The stylesheet does NOT allow 10 digit NDCs (i.e., to the pack level).
- This does not apply to all SPL – it is dependent on marketing category, document type etc. **Currently, this validation rule applies to CDER products only.** The goal of this rule is to establish a clear supply chain for each product.
- There has been discussion about whether this validation rule will eventually change to an association down to the pack level. Also about which business operations are impacted.
- Internal discussions ongoing at FDA around listing inner packs separately.
- Questions are being collected and sent back to DRLS.

Duplicate file deletion:

Process for deleting duplicate files – new option possibly

In response to the request to automate the process of archiving SPL R3 or duplicate SPL R4 documents on DailyMed sans the requirement to add the marketing status and marketing start and end dates (SPL R3) or the update of the marketing status to "completed" and entry of a marketing end date (**duplicate** SPL R4) and to honor industry requests (received from 2005 - 2009) regarding drug companies' opposition to the FDA's system altering the data elements in drug companies' SPL files, here is the solution which will afford an opportunity for SPL document authors to archive on DailyMed SPL R3 documents which need to be "retired" and instances of SPL R4 documents, which due to the combination of package inserts, need to be archived on DailyMed.

Send questions or concerns to spl@fda.hhs.gov by January 20, 2012

The Technical Team will discuss these at the January 30, 2012.

Target implementation: February 2012 (once concerns are addressed).

FYI:

- DUNS portal: Jean confirmed with D&B that they are still working on the portal but have been delayed. They will get back to us next week with new timing.
- New training manual expected in the near future for Xforms.

Schedule for the 2012 SPL training sessions:

Webinars, Telephone call-in sessions:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>.

Note on Telephone call-in sessions: These don't restart for 2012 until January 23.

Next scheduled teleconference: February 8, 2012

REPRINT of ER/DL text of additional questions

Questions in black text

Responses from Paul Loebach and Lonnie Smith are in red text

New Data Relationship for CDER products -- link between product NDC and establishments/business operation:

Each product NDC code must be linked to at least one establishment in the SPL. The focus of discussion/questions in the past has been related to establishments that manufacture drug product. In the December teleconference, CDER recommended that product NDCs be linked to all appropriate establishments.

1. Which SPL document types and marketing categories are required to have NDC product links.

- Which SPL document types?

- Which marketing categories?

Document types:

All documents that apply to CDER products – Human Prescription and OTC – including but not limited to:

- o Human Prescription Drug Label
- o Human OTC Drug Label
- o Bulk Ingredient

Marketing categories: All that pertain to CDER products, including

- o NDA, ANDA
- o Drug for further processing
- o Approved drug product manufactured exclusively for PLD
- o Etc.

Note: Bulk ingredient and contract manufacturers may not be aware that this data rule is being implemented on Feb 1st. Therefore, to avoid potential issues with SPL validation and import, sponsors should advise establishments in their supply chain of this new requirement.

2. Please confirm which business operations will be required to have links to product NDC codes.

Specific questions include:

- Are product NDCs required only for those establishments with a business operation of “manufacture”...or for all business operations?
- API and analytical sites?
- Pack/label? In many situations, the differences are seen at the pack level, and only product level NDCs can be entered. Thus would you enter the same NDC code for multiple pack/label establishments.

The data relationship is between the establishment/business operation and the product NDC codes

- Every product NDC must be linked to at least 1 establishment/business operation
- Every establishment/business operation must be linked to at least 1 product NDC.

FDA recommends that all products be linked to all relevant establishment/business operation. They realize this is extra work, but the goal is to document the supply chain – for purposes of inspections, etc. .

The validation program can only check to make sure that each product NDC is linked to one establishment and vice versa. However, labelers should include all data relationships for each establishment, by business operation. For example,

- Establishments with a business operation of “API manufacture” should include all product NDC codes.

- Pack / label sites will include the NDC product code, even though all pack sizes may not be manufactured there.

3. Is there any “talk” about eventually taking this validation rule down to the pack level? Pharma would prefer to know sooner rather than later -- ie we don’t want to go to all the work of collecting the data and putting product NDCs in the SPL now, and then have to redo this later to the pack level.

At this time there are no plans to go to the NDC pack level. FDA acknowledges that this does not provide complete information at the pack/label level. FDA decided that the product NDC code was a good compromise.

4. FDA communications have stated that this new data relationship is for CDER regulated products. What if sponsors put the data into SPL for CBER or CVM products? Will the SPL still pass validation?

For CBER products, the SPL will pass validation.

For CVM, the SPL will not pass validation. Sponsors will have to correct the SPL to take out the data.

Images that should be included in the SPL file:

5. Please confirm which packaging label images should be included – ie container label and/or carton (inner and outer packaging, etc.). Companies have received different information from the FDA and are providing different labeling images:

- both container and carton labels.
- partial carton and container label
- carton label (if too big divide into 2 parts)

The regulations state that companies need to submit a “representative sample” of the labeling, where representative sample means that labels do not have to be submitted if the labels differ only in the quantity of contents statement. FDA will leave the interpretation of “representative sample” to each company. However, the labeler should consider what is practical to include in the SPL. The larger the SPL package, the harder it will be to download, for example, to a mobile device.

Do all package sizes for a product need to be included in the SPL?

- No. Per regulations, only a representative sample should be included – ie one label for a particular strength when the difference is only in the contents statement.

Should both the container and carton labels be included in the SPL?

- No, the regulations state to include a representative sample.
- The goal of this requirement is to make the information on the label available to the reader.

Providing both the inner and outer labels is simply a duplication of information.

What if the carton is too big to be legible in the SPL?

- Divide the image of the carton into 2 or more jpg images, so that the information on the label is readable.

Other:

6. This data relationship and validation rule has been in the IG for a long time, but has not been implemented. There are many other rules in the IG that have not yet been implemented.

- a. Are any plans to implement any other validation rules that pharma should be aware of that are planned to be implemented in the near future?
- b. Special note: We (ie pharma manufacturers/labels) would appreciate having specific notification of when new rules will be implemented – with enough notice such that we can communicate with our vendors to assure that the new release can be implemented effectively.

There are no data rule changes planned in the near future. FDA heard industry's recent comments about

providing notice of changes, and FDA will try to be more communicative in the future.

Per the SPL Project Lead:

- FDA will be checking to make sure that all establishments register every year. An SPL may fail validation if one of the establishments has not registered for the previous year [Registrations must be completed by December 31 of each year.]

- Validation procedures and "common errors" documents will be kept up to date – every quarter. FDA is planning to put notations in these document to highlight "this is new" since the last version.